

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

302 658 9200
302 658 3989 FAX

MARY B. GRAHAM
(302) 351-9199
mgraham@mnat.com

March 26, 2007

VIA E-FILING

The Honorable Gregory M. Sleet
United States District Court
Federal Building
844 North King Street
Wilmington, DE 19801

Re: *Merck & Co., Inc. v. Apotex, Inc.*
C.A. No. 06-230

Dear Judge Sleet:

The Court may recall that, in a teleconference on February 9, 2007, the Court addressed the issue of whether discovery should be stayed pending its ruling on Merck's motion to dismiss for lack of subject matter jurisdiction in view of Merck's covenant not to sue, and whether Merck was required to provide certain discovery sought by Apotex (interrogatories directed to contentions on the merits and certain depositions). At the end of the teleconference, the Court indicated that it was amenable to allowing the parties to attempt to develop, and get back to the Court with, a proposed procedure that would allow the Court to reach the merits of this case in the event it were to decide that there is subject matter jurisdiction and that would resolve the discovery issues.

The parties have now agreed upon a stipulation and proposed order, subject to the approval of the Court, that would pertain to the proceedings (including to suspend discovery) and a proposed form of judgment subject to immediate appeal (for entry in the event the Court were to decide that it has subject matter jurisdiction) which are attached. We would appreciate the opportunity to present these papers to the Court and to discuss the status of the case, in follow up to our teleconference on February 9.

The Honorable Gregory M. Sleet

March 26, 2007

Page 2

Respectfully,

/s/ Mary B. Graham

Mary B. Graham (#2256)

MBG/dam

Enclosures

cc: Louise Walsh, Esquire (via e-mail)
Richard L. Horwitz, Esquire (via e-mail)
Nicolas G. Barzoukas, Esquire
John F. Lynch, Esquire

774743

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)	
)	
Plaintiff,)	
v.)	C.A. No. 06-230 (GMS)
)	
APOTEX, INC.,)	
)	
Defendant.)	
_____)	

STIPULATION [AND PROPOSED ORDER]

The parties, Plaintiff Merck & Co., Inc. (“Merck”) and Defendant Apotex, Inc. (“Apotex”), hereby stipulate, subject to the approval of the Court, that:

1. Subject to the Court having subject matter jurisdiction, Merck will waive its right to present any evidence of infringement against Apotex in this action and, in accordance with the covenant not to sue it has provided to Apotex, will not assert infringement for any claims of the patents in suit in connection with ANDA No. 077-982, in its present form.
2. Upon the determination that the Court has subject matter jurisdiction, the parties will seek to have the Court issue an immediately appealable judgment in the form attached hereto as Exhibit A.
3. Apotex will withdraw the motion to file its Amended Answer and Counterclaims.
4. Discovery, including expert discovery, is suspended as of February 9, 2007.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
302.658.9200

Attorneys for Merck & Co., Inc.

POTTER ANDERSON & CORROON LLP

/s/ Kenneth L. Dorsney

Richard L. Horwitz (#2246)
Kenneth L. Dorsney (#3726)
Hercules Plaza, 6th Floor
1313 North Market Street
P.O. Box 951
Wilmington, DE 19899
302.984.6000

Attorneys for Apotex, Inc.

SO ORDERED this ____ day of _____, 2007.

UNITED STATES DISTRICT JUDGE

777803

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)	
)	
Plaintiff,)	
v.)	C.A. No. 06-230 (GMS)
)	
APOTEX, INC.,)	
)	
Defendant.)	
)	

[PROPOSED] FINDINGS OF FACT AND FINAL JUDGMENT

WHEREAS, by order of _____, 2007, the Court has determined that it has subject matter jurisdiction in this case and accordingly may enter a judgment on infringement;

WHEREAS, in its complaint, Plaintiff Merck & Co., Inc. (“Merck”) has asserted that Defendant Apotex, Inc. (“Apotex”) has infringed certain of its patents by virtue of Apotex’s filing of an Abbreviated New Drug Application (“ANDA”) No. 077-982 for a generic version of alendronate pursuant to 35 U.S.C. § 271(e)(2)(A), namely U.S. Patent Nos. 5,358,941 (“the ‘941 Patent”), 5,681,590 (“the ‘590 Patent”), 6,090,410 (“the ‘410 Patent”), 6,194,004 (“the ‘004 Patent”), 5,894,726 (“the ‘726 Patent”), 6,008,207 (“the ‘207 Patent”), 5,994,329 (“the ‘329 Patent”), 6,015,801 (“the ‘801 Patent”), and 6,225,294 (“the ‘294 Patent”);

WHEREAS, because Merck asserts that the Court lacks subject matter jurisdiction over this case, Merck has waived the right to present any evidence of infringement in the event the Court has subject matter jurisdiction;

WHEREAS, the Court’s Final Judgment in this action will be immediately appealable;

WHEREAS, based on the record in front of this Court:

1. The claims of the '941 Patent recite a composition comprising the excipients: anhydrous lactose; microcrystalline cellulose; croscarmallose sodium; and magnesium stearate.

2. The product that is the subject of Apotex's ANDA No. 077-982 does not contain anhydrous lactose or croscarmallose sodium.

3. Consequently, there is no literal infringement of any of the claims of the '941 Patent and Merck has waived the right to present any evidence of infringement under the doctrine of equivalents.

4. The claims of the '590 Patent recite a process for preparing a composition comprising "a diluent, selected from: anhydrous lactose and hydrous fast flow lactose" or a composition comprising "excipients consisting essentially of: hydrous fast flow lactose; microcrystalline cellulose; croscarmallose sodium; and magnesium stearate."

5. The product that is the subject of Apotex's ANDA No. 077-982 does not contain lactose, either anhydrous or hydrous fast flow; nor does it contain croscarmallose sodium.

6. Consequently, there is no literal infringement of any of the claims of the '590 Patent and Merck has waived the right to present any evidence of infringement under the doctrine of equivalents.

7. The claims of the '410 Patent recite a composition comprising "excipients comprising: a diluent selected from the group consisting of anhydrous lactose and hydrous fast flow lactose."

8. The product that is the subject of Apotex's ANDA No. 077-982 does not contain lactose, either anhydrous or hydrous fast flow.

9. Consequently, there is no literal infringement of any of the claims of the '410 Patent and Merck has waived the right to present any evidence of infringement under the doctrine of equivalents.

10. The claims of the '004 Patent recite a composition comprising "excipients comprising a diluent selected from the group consisting of anhydrous lactose and hydrous fast flow lactose."

11. The product that is the subject of Apotex's ANDA No. 077-982 does not contain lactose, either anhydrous or hydrous fast flow.

12. Consequently, there is no literal infringement of any of the claims of the '004 Patent and Merck has waived the right to present any evidence of infringement under the doctrine of equivalents.

13. The claims of the '726 Patent recite a composition comprising anhydrous alendronate and a method for treating and/or preventing bone loss in a subject comprising administering the composition comprising anhydrous alendronate.

14. The product that is the subject of Apotex's ANDA No. 077-982 does not contain anhydrous alendronate, but rather is the monosodium salt trihydrate form.

15. Consequently, there is no literal infringement of any of the claims of the '726 Patent and Merck has waived the right to present any evidence of infringement under the doctrine of equivalents.

16. The claims of the '207 Patent recite methods comprising administering a therapeutically effective amount of anhydrous alendronate.

17. The product that is the subject of Apotex's ANDA No. 077-982 does not contain anhydrous alendronate, but rather is the monosodium salt trihydrate form.

18. Consequently, there is no literal infringement of any of the claims of the '207 Patent and Merck has waived the right to present any evidence of infringement under the doctrine of equivalents.

19. The claims of the '801 Patent recite methods for treating or preventing a group of diseases consisting of Paget's disease, abnormally increased bone turnover, periodontal disease, tooth loss, bone fractures, metastatic bone disease, hypercalcemia of malignancy and multiple myeloma, by administering a bisphosphonate, such as alendronate, at a reduced frequency dosing schedule including once-weekly, twice-weekly, biweekly, and twice-monthly.

20. In Apotex's ANDA No. 077-982, the recommended uses of alendronate are for osteoporosis and Paget's disease.

21. Merck has waived its right to present any evidence of infringement, consequently, there is no literal infringement or infringement under the doctrine of equivalents for any of the claims of the '801 Patent.

22. The claims in the '329 Patent relate generally to methods and kits for inhibiting bone resorption and methods for treating and preventing osteoporosis by administering a bisphosphonate at a reduced-frequency dosing schedule including once-weekly dosing.

23. Merck has waived its right to present any evidence of infringement, consequently, there is no literal infringement or infringement under the doctrine of equivalents for any of the claims of the '329 Patent.

24. The claims in the '294 Patent relate generally to "kits" containing a unit dosage of a bisphosphonate for administration according to a reduced-frequency dosing schedule including once-weekly dosing.

25. Merck has waived its right to present any evidence of infringement, consequently, there is no literal infringement or infringement under the doctrine of equivalents for any of the claims of the '294 Patent.

26. Accordingly, based on the foregoing findings of fact and conclusions of law, the Court has found on the merits that the patents asserted by Merck, namely U.S. Pat. Nos. 5,358,941, 5,681,590, 6,090,410, 6,194,004, 5,894,726, 6,008,207, 5,994,329, 6,015,801, and 6,225,294, are not infringed by the product that is the subject of Apotex's ANDA No. 077-982:

IT IS HEREBY ORDERED THAT:

1. This Court has jurisdiction over the parties and the subject matter of this case.

2. Judgment of noninfringement as to all the patents asserted in this case, namely U.S. Pat. Nos. 5,358,941, 5,681,590, 6,090,410, 6,194,004, 5,894,726, 6,008,207, 5,994,329, 6,015,801, and 6,225,294, is entered in favor of Apotex and against Merck on Merck's claims and Apotex's counterclaim with respect to Apotex's filing of ANDA 077-982 and with respect to the manufacture, sale, offer for sale, use or importation of the products for which approval is sought through the filing of ANDA 077-982.

3. Apotex's counterclaim related to invalidity is dismissed without prejudice.

4. Apotex's motion for leave to file its First Amended Answer, Affirmative Defenses, and Counterclaims is denied without prejudice.

5. This Judgment and Order is final and disposes of all claims and counterclaims in this action and is immediately appealable.

6. Each party shall bear its own costs, attorneys' fees, and expenses incurred in connection with this case.

SO ORDERED this _____ day of _____, 2007.

UNITED STATES DISTRICT COURT JUDGE

774484